

APR - 2 1998

**PT. EKA WIRA ASIA****Jl. Haji Zainal Arifin 128 B-C
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K980729

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SUMMARY OF 510(K) SUBMISSION # K980729

(1) Name of applicant : Mr. Hansen Laurence

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Phone No. 62-61-328888; 62-61-730008
Fax No. 62-61-520588; 62-61-730007

The contact persons within the firm as well as in U.S.A. are given below:

Contact person in firm : Mr. Hansen Laurence
Fax No. 62-61-520588; 62-61-730007Contact person in U.S.A. : Emmy Tjoeng
Fax No. 562-693-8866

(2) Device details

Trade Name : Private Label - Nitrile Examination Gloves
Pre-Powdered, Blue and White Color

Classification Name : Patient Examination Gloves

Product Code : Nitrile 80 LZA

(3) Equivalent device
legally marketed: Class I Nitrile Examination Gloves 80 LZA Pre-Powdered
meeting ASTM D 3578 - 95

(4) Intended use

: A patient examination glove is a disposable device intended
for medical purpose that is worn on examiner's hand or finger
to prevent contamination between patient and examiners.



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(5) Technological characteristic of the gloves.

g. Dimensions

SIZES	SMALL	MEDIUM	LARGE
Length (min) mm	240	240	240
Palm width mm	85 ± 10	95 ± 10	111 ± 10
Thickness			
1. Cuff (min)	0.1	0.1	0.1
2. Palm (min)	0.1	0.1	0.1
3. Fingertip (min)	0.1	0.1	0.1

h. Physical Properties

	Before Aging	After Aging at 100° for 22 hrs
Tensile Strength	14 Mpa	14 Mpa
Ultimate Elongation (min)	700 %	500 %

i. Performance Requirement Characteristic

	Related defeats	Inspection Level	AQL
Watertightness	Holes	S - 4	2.5
Dimension	Width, length Thickness	S - 2	4
Physical Properties	Before & After Aging	S - 2	4

j. Weight of residual powder in medium size gloves: 150 ± 50 mg

k. Bio-Compatibility (attached) Annexure XII

l. Test Results as per ASTM D 3578 - 95 (attached) Annexure V

(6) Performance data is the same as mentioned immediately above.

(7) Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

(8) Non-clinical data

Gloves meet or exceed the ASTM Standard.
Meet FDA pin holes requirement.
Meet labeling claim.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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PT. Eka Wira Asia
C/O Ms. Emmy Tjoeng
Official Correspondent for PT, Eka Wira Asia
Glove Source, Incorporated
12110 East Slauson Avenue #3
Santa Fe Springs, California 90670

Re: K980729
Trade Name: Nitrile Examination Gloves - Powdered Blue
and White
Regulatory Class: I
Product Code: LZA
Dated: February 23, 1998
Received: February 25, 1998

Dear Ms. Tjoeng:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

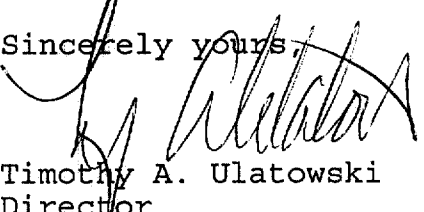
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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ANNEXURE II

INDICATION FOR USE

Applicant : Mr. Hansen Laurence

510(k) Number : K980729

Device Name : Nitrile Patient Examination Gloves - Powder
Blue and White Color

Indication for use :

A patient examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiners.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The Counter-Use X
(Optional Format 1-2-96)
(Division Sign-Off)Division of Dental, Infection Control,
and General Hospital Devices510(k) Number K 980729

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FACTORY : JL. RAYA MEDAN - NAMORAMBE PS. IV KAB. DELI SERDANG